

Approval Date _____

FREEDOM OF INFORMATION SUMMARY

CAPSTAR® (nitenpyram) Tablets

Supplemental NADA 141- 175

Novartis Animal Health US, Inc.

Greensboro, NC 27408

This New Animal Drug Application is for the concurrent use of CAPSTAR® Tablets with either SENTINEL® Flavor Tabs® or PROGRAM® Flavor Tabs® to kill adult fleas and prevent flea eggs from hatching. The effects of SENTINEL® Flavor Tabs® or PROGRAM® Flavor Tabs® which control flea populations, and CAPSTAR® Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM™.

NADA 141-175

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1. GENERAL INFORMATION:

- a. File Number: NADA 141-175
- b. Sponsor: Novartis Animal Health US, Inc.
3200 Northline Ave., Suite 300
Greensboro, NC 27408
Drug Labeler Code: 058198
- c. Established Name: Nitenpyram
- d. Proprietary Name: CAPSTAR® Tablets
- e. Dosage Form: Oral tablets
- f. How Supplied: CAPSTAR® Tablets are available in two tablet sizes (see Dosage section) formulated according to the weight of the dog or cat. Each tablet size is available in color-coded packages containing six tablets.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Refer to the dosage section.
- i. Route of Administration: Oral
- j. Species/Class: Dogs and Cats

k. Recommended Dosage:

CAPSTAR[®] Tablets should be administered according to the Recommended Dosage Schedule below. **Weigh your pet prior to administration to ensure proper dosage.** Do not administer to pets under 2 pounds. A single dose of CAPSTAR[®] should kill the adult fleas on your pet. If your pet gets reinfested with fleas, you can safely give another dose as often as once per day.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram mg/Tablet
Dog or Cat	2 - 25 lbs	One tablet	11.4 mg
Dog	25.1 - 125 lbs	One tablet	57 mg

The dosage schedule for the concurrent use of CAPSTAR[®] Tablets and SENTINEL[®] Flavor Tabs[®] is addressed in NADA 141-204.

The dosage schedule for the concurrent use of CAPSTAR[®] Tablets and PROGRAM[®] Flavor Tabs[®] is addressed in NADA 141-205.

l. Pharmacological Category:

Nitenpyram is a flea adulticide.

m. Indications:

CAPSTAR[®] Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens four weeks of age and older and 2 pounds of body weight or greater.

n. Effect of Supplement:

Approval of this supplemental NADA will change the labeling for NADA 141-175.

1. The text in the “Indications” section is changed to include the words “kill adult fleas.” The section will now read:
“CAPSTAR[®] Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.” This change makes the labeling more consistent with labeling for other approved products that kill adult fleas.
2. There are some minor revisions to clarify the currently approved text in the package insert and the unit dose cartons.
3. The package insert is revised to include reference to the concurrent use of PROGRAM[®] (lufenuron) Flavor Tabs[®] (NADA 141-035) to kill adult fleas and prevent flea eggs from hatching. The information supporting approval for this concurrent use is documented in NADA 141-205.
4. The package insert is revised to refer the reader to a veterinarian for information about the concurrent use of SENTINEL[®] (milbemycin oxime/lufenuron) Flavor Tabs[®] (NADA 141-084), to kill adult fleas and prevent flea eggs from hatching. SENTINEL[®] Flavor Tabs[®] are a prescription product. The information supporting approval for this concurrent use is documented in NADA 141-204.
5. The unit dose cartons are revised to refer to concurrent use with PROGRAM[®] (lufenuron) Flavor Tabs[®].
6. Each unit dose carton will contain an additional “FLEA MANAGEMENT SYSTEM[™]” package insert that provides specific information for using CAPSTAR[®] Tablets with PROGRAM[®] (lufenuron) Flavor Tabs[®].

2. EFFECTIVENESS:

- a. For information about the effectiveness of CAPSTAR® Tablets please refer to the FOI summary for the original approval dated October 20, 2000 (A-0000).
- b. For information about the effectiveness of the concurrent use of CAPSTAR® Tablets with PROGRAM® Flavor Tabs® please refer to the FOI summary for NADA 141-205.
- c. For information about the effectiveness of the concurrent use of CAPSTAR® Tablets with SENTINEL® Flavor Tabs® please refer to the FOI summary for NADA 141-204.

3. TARGET ANIMAL SAFETY:

- a. For information about the safety of CAPSTAR® Tablets please refer to the FOI summary for the original approval dated October 20, 2000 (A-0000).
- b. For information about the safety of the concurrent use of CAPSTAR® Tablets with PROGRAM® Flavor Tabs® please refer to the FOI summary for NADA 141-205.
- c. For information about the safety of the concurrent use of CAPSTAR® Tablets with SENTINEL® Flavor Tabs® please refer to the FOI summary for NADA 141-204.

4. HUMAN SAFETY:

This drug is intended for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children."

5. AGENCY CONCLUSIONS:

The data in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that CAPSTAR® Tablets, when administered in accordance with the directions provided by the revised labeling, are safe and effective for the treatment of flea infestations on dogs, puppies, cats, and kittens.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the concurrent use with SENTINEL[®] (milbemycin oxime/lufenuron) Flavor Tabs[®] and concurrent use with PROGRAM[®] (lufenuron) Flavor Tabs[®] for which this supplement is approved.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

CAPSTAR[®] is under the following U.S. patent number: 5,750,548
Date of Expiration: April 29, 2016.

6. ***ATTACHMENTS:***

Facsimile Labeling is attached as indicated below.

- a. CAPSTAR[®] Package Insert
- b. Unit Dose Cartons - 11.4 mg, 57 mg

CAPSTAR®

(NITENPYRAM)

CAPSTAR® is an oral tablet for dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

Active Ingredients

CAPSTAR Tablets contain 11.4 or 57.0 mg of nitenpyram, which belongs to the chemical class of neonicotinoids. Nitenpyram kills adult fleas.

Warnings

Not for human use. Keep this and all drugs out of the reach of children.

Directions

CAPSTAR Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

A single dose of CAPSTAR should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

To give CAPSTAR Tablets, place the pill directly in your pet's mouth or hide it in food. If you hide the pill in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Treat all infested pets in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

Dosage

CAPSTAR Tablets should be administered according to the following schedule. **Weigh your pet prior to administration to ensure proper dosage.** Do not administer to pets under 2 pounds.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram per Tablet
Dog or Cat	2-25 lbs.	One tablet	11.4 mg
Dog	25.1-125 lbs.	One tablet	57.0 mg

*Please see separate insert in this package for concurrent dosing of CAPSTAR Tablets and PROGRAM® (lufenuron) Flavor Tabs®.

Adverse Reactions

Laboratory and clinical studies showed that CAPSTAR Tablets are safe for use in dogs and cats, puppies and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

Other Information

CAPSTAR Tablets begin working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.

CAPSTAR Tablets are safe for pregnant or nursing dogs and cats.

When using this product, you may notice that your dog or cat will start scratching itself as fleas begin to die. The scratching behavior is temporary and is a reaction to the fleas, not the drug.

CAPSTAR Tablets kill adult fleas that cause flea allergy dermatitis (FAD).

CAPSTAR Tablets may be used together with other products, including heartworm preventives, corticosteroids, antibiotics, vaccines, de-worming medications, shampoos and other flea products.

Flea Infestations on Dogs and Cats

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations is important to your pet's health and also reduces the problems associated with these parasites.

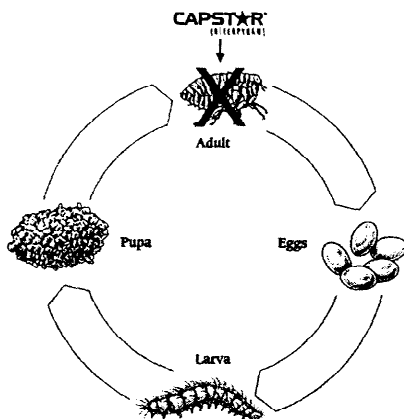
CAPSTAR Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in

and around the home will continue to develop into adults that can reinfest your pet.

In addition to killing adult fleas with Capstar, you can treat your pet with an insect development inhibitor like PROGRAM Flavor Tabs to prevent and control flea populations. Please see the separate PROGRAM Flavor Tabs/CAPSTAR Tablets FLEA MANAGEMENT SYSTEM™ insert included in this package for information on how to use these two products together to kill adult fleas and prevent flea eggs from hatching. For information on how to use SENTINEL Flavor Tabs (for dogs only) with CAPSTAR Tablets, see your veterinarian.

The following diagram illustrates the flea's life cycle and where CAPSTAR Tablets work:

Life Cycle of the Flea



Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your pet and subsequently lay eggs, which drop off your pet's coat. Within days, larvae hatch from the eggs and live undetected in your pet's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto your pet to continue the life cycle. When these new fleas are seen on your pet, treat with CAPSTAR Tablets.

After reading this insert, if you have any questions about flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.

Storage Conditions

Store at controlled room temperature, between 59° and 86°F (15-30°C).

Questions? Comments?
Please Call 1-800-332-2761

Visit our website at www.petwellness.com

Manufactured for: Novartis Animal Health US, Inc.
Greensboro, NC 27408

NADA #141-175, Approved by FDA.

U.S. Patent # 5,750,548

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CAPSTAR BLUE WITH SWOOSH

CAPSTAR®
(NITENPYRAM)

FAST ACTING:
Begins working within
30 minutes.

CAPSTAR®
(NITENPYRAM)

FOR DOGS AND CATS 2 TO 25 lbs.

NOVARTIS

CAPSTAR
(NITENPYRAM)

CAPSTAR
(NITENPYRAM)

FAST ACTING:
Begins working within
30 minutes.

LOT
EXP

CAPSTAR
(NITENPYRAM)

CAPSTAR
(NITENPYRAM)

Warnings:

Keep this and all drugs out of the reach of children.

Directions:

A single dose of CAPSTAR® Tablets should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

Please refer to the package insert for complete information.

Other information:

- CAPSTAR is safe for use in dogs, puppies, cats and kittens 4 weeks of age and older, and 2 pounds of body weight or greater. Weigh your pet prior to administration to ensure proper dosage. It is also safe for use in pregnant or breeding dogs and cats.
- Begins working within 30 minutes. In studies, CAPSTAR achieved greater than 50% effectiveness against adult fleas on dogs within 4 hours and cats within 12 hours.
- CAPSTAR can be used with Ivermectin to provide FLEA MANAGEMENT SYSTEM, the two products when used together kill adult fleas and prevent new eggs from hatching.
- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- If you have questions about flea control or medical problems associated with flea infestations, please consult your veterinarian.
- Questions or Comments?
Please call 1-800-332-2761.
- Store at controlled room temperature, between 59° and 86°F (15°-30°C).

Made in Canada.
www.pvetbusiness.com
1-800-332-2761

NOVARTIS

CAPSTAR GREEN WITH SWOOSH

CAPSTAR

LOT
EXP

CAPSTAR

(NITENPYRAM)

Warnings:

Keep this and all drugs out of the reach of children.

Directions:

- A single dose of CAPSTAR Tablets should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.
- Please refer to the package insert for complete information.

Other Information:

- CAPSTAR is safe for use in dogs, puppies, cats and kittens 4 weeks of age and older, and 2 pounds of body weight or greater. Weigh your pet prior to administration to ensure proper dosage. It is also safe for use in pregnant or breeding dogs and cats.
- Begins working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.
- CAPSTAR can be used with Ivermectin to provide a FLEA MANAGEMENT SYSTEM. The two products when used together kill adult fleas and prevent flea eggs from hatching.
- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- If you have questions about flea control or medical problems associated with flea infestations, please consult your veterinarian.
- Questions or Comments? Please call 1-800-332-2761.
- Store at controlled room temperature, between 59° and 86°F (15°-30°C).

Made in Canada.
www.petwellness.com
NADA 141-375/000/72

NOVARTIS

FOR DOGS OVER 25 lbs.

CAPSTAR
(NITENPYRAM)

FAST ACTING:
Begins working within
30 minutes.

For Treatment of Flea Infestation, CAPSTAR
FAST ACTING: Begins working within 30 minutes.

6 TABLETS (containing Nitenpyram, each)
NADA 141-375/000/72, approved by the FDA Product ID 00072

NOVARTIS

CAPSTAR
(NITENPYRAM)

FAST ACTING:
Begins working within
30 minutes.

CAPSTAR
(NITENPYRAM)